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Melissa Stagner

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August 26, 2005

Date of Signature

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Chiklis et al.

Examiner: Louise Z. Wang

Filed: October 17, 2001

Art Unit: 1648

Serial No. 09/981,506

For: Nucleic Acid Amplification Controls

### AMENDMENT AND RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Applicants respond as follows to a communication dated July 26, 2005, subjecting the claims to a Restriction requirement.

Applicants have amended claim 18 herein and respectfully request the Examiner to reconsider the restriction for the following reasons.

The Examiner deems the application to contain 6 different groups. It is respectfully requested that the Examiner reconsider the restriction with respect to groups I and V. The Examiner contends that these are different invention because the surface modified microorganisms of Group I can be used in a different method. It is respectfully pointed out that no such use has been disclosed or claimed by the Applicants. It is not clear to the Applicants how the microorganisms of the present invention, in which the nucleic acids are substantially intact so as to be amenable to amplification, can be used for

therapeutic treatment of diseases. The Examiner is therefore respectfully requested to reconsider since Group II claims contain all the limitations of Group I claims.

With respect to Groups I and III, the Examiner contends that these groups are distinct because chemical modification methods as claimed in Invention III can be used to make derivatives of pharmaceutical drug compounds or any protein. Again, the Examiner's attention is respectfully directed to claim 18 of Group III as amended herein which states that the method comprises a step of irreversibly modifying one or more surface proteins while leaving the nuclear components substantially intact. The term substantially intact is defined in the specification to mean that the nucleic acids are amenable to amplification. Again, it is not clear to the Applicants how this limitation of the method can be extended to isolated molecules such as pharmaceutical drugs or proteins. The Examiner is respectfully requested to reconsider since Group III claims contain all the limitations of Group I microorganisms.

Based on the above, Applicants respectfully request the Examiner to rejoin Groups I, III and V. However, as required under 35 USC 121, Applicants provisionally elect Group I.

Further, the Examiner has required an election of species within the elected group. As required under 35 USC 121, Applicants provisionally elect formaldehyde as the chemical compound and human immunodeficiency virus (HIV) as the microorganism.

The amendment to claim 18 and the complete set of pending claims are presented on the accompanying pages.